Computed Tomography to Detect Coronary Calcification

Policy # 00031  
Original Effective Date: 10/21/2002  
Current Effective Date: 01/06/2014

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Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of electron-beam computed tomography (EBCT) or spiral computed tomography (CT) to detect coronary artery calcification to be investigative.*

Background/Overview
Electron beam computed tomography (also known as ultrafast CT) uses an electron gun rather than a standard x-ray tube to generate x-rays, thus permitting very rapid scanning. Spiral CT scanning (also referred to as helical CT scanning) also creates images at greater speeds by rotating a standard x-ray tube around the patient such that data are gathered in a continuous spiral or helix rather than in individual slices.

While both EBCT and spiral CT scanning may be valued as an alternative to conventional CT scanning due to their faster throughput, their speed of image acquisition also permits unique imaging of the moving heart. For example, the rapid image acquisition time virtually eliminates motion artifact related to cardiac contraction, permitting visualization of the calcium in the epicardial coronary arteries. Electron beam computed tomography software permits quantification of calcium area and density, which are translated into calcium scores. Calcium scores have been investigated as a technique for detecting coronary artery calcification, both as a diagnostic technique in symptomatic patients to rule out an atherosclerotic etiology of symptoms or, in asymptomatic patients, as an adjunctive method for risk stratification for coronary artery disease (CAD).

Electron beam computed tomography and multi-detector computed tomography (MDCT) were initially the primary fast CT methods for measurement of coronary artery calcification. A fast CT study for coronary artery calcium measurement generally takes 10 to 15 minutes and requires only a few seconds of scanning time. More recently, CT angiography has been used to assess coronary calcium. Because of the basic similarity between EBCT and CT angiography in measuring coronary calcium, it is expected that CT angiography provides similar information on coronary calcium as does EBCT.

Rationale/Source
The rationale for measuring calcium in coronary arteries is that it measures coronary atherosclerosis. Coronary calcium is present in coronary atherosclerosis, but the atherosclerosis detected may or may not be causing ischemia or symptoms. Such a measure may be correlated with the presence of critical coronary stenoses or serve as a measure of the patient’s proclivity toward atherosclerosis and future coronary disease. Thus, it could serve as a variable to be used in a risk assessment calculation for the purposes of determining appropriate preventive treatment in asymptomatic patients. Alternatively, in other clinical scenarios, it might help determine whether there is atherosclerotic etiology or component to the presenting clinical problem in symptomatic patients, thus helping to direct further workup for the clinical problem.

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second scenario, a calcium score of zero usually indicates that the patient’s clinical problem is unlikely to be due to atherosclerosis and that other etiologies should be more strongly considered. In neither case does the test actually determine a specific diagnosis. Most clinical studies have examined the use of coronary calcium for its potential use in estimating the risk of future coronary heart disease (CHD) events.

Coronary calcium levels can be expressed in many ways. The most common method is the Agatston score, which is a weighted summed total of calcified coronary artery area observed on CT. This value can be expressed as an absolute number, commonly ranging from 0 to 400. These values can be translated into age and sex-specific percentile values. Different imaging methods and protocols will produce different values based on the specific algorithm used to create the score, but the correlation between any 2 methods appears to be high, and scores from one method can be translated into scores from a different method.

This policy is based, in part on a 1998 TEC Assessment.

**Coronary Calcium for Coronary Disease Risk Stratification**

Many prospective studies have shown evidence for predictive capacity of calcium scores in addition to assessment of traditional risk factors. In a study of 1,029 asymptomatic adults with at least one coronary risk factor, Greenland et al. showed that a calcium score of greater than 300 predicted increased risk of cardiac events within Framingham risk categories. A study by Arad et al. showed similar findings in a population-based sample of 1,293 subjects who had both traditional risk factors and calcium scores evaluated at baseline. A study by Taylor et al. studied the association of the Framingham risk score and calcium scores in a young military population (mean age 43 years). Although only nine acute coronary events occurred, calcium scores were associated with risk of events while controlling for the risk score. LaMonte et al. also analyzed the association of calcium scores and CHD events in 10,746 adults. In this study, coronary risk factors were self-reported. During a mean follow-up of 3.5 years, 81 CHD events occurred. Similar to the other studies, the relationship between calcium scores and CHD events remained after adjustment for other risk factors. Other studies show similar findings. Additional studies have defined how the incorporation of calcium scores into risk scores changes risk prediction. In a study by Polonsky et al., incorporation of calcium score into a risk model resulted in more subjects (77% vs. 66%) being classified in either high-risk or low-risk categories. The subjects who were reclassified to high risk had similar risk of CHD events as those who were originally classified as high risk. A study by Elias-Smale et al. showed similar findings; reclassification of subjects occurred most substantially in the intermediate risk group (5-10% 5-year risk) where 56% of persons were reclassified.

A growing body of literature now addresses the relationship of traditional risk factors, calcium scores, and risk of CHD. Current treatment guidelines for coronary disease prevention recommend specific treatment based on prediction of coronary disease risk. The cited studies enrolled different populations, assessed different traditional risk factors, and assessed different coronary disease outcomes. Different calcium score cutoffs were analyzed in the studies. Given the variation in the studies, the magnitude of increased risk conferred by a given calcium score is still uncertain. The results of the study by Greenland et al. would suggest that a high calcium score, as defined as a score greater than 300, does not change risk appreciably for those with Framingham risk scores less than 10% or greater than 20%. Given that there is no direct evidence that risk stratification using calcium scores in addition to traditional risk assessment improves...
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Patient outcomes, a consensus approach that integrates existing evidence with a modeling approach to predicting patient outcomes would aid in determining whether calcium scoring is of value.

Numerous studies have also evaluated the predictive ability of coronary calcium using CT angiography. These studies have included different population, such as patients with or without risk factors or patients with an intermediate risk of CAD. Similar to studies that use EBCT, these studies have demonstrated that calcium scores derived from CT angiography provide incremental predictive information for the overall risk of CAD, as compared to coronary angiography and for the future occurrence of major cardiac events.

**Coronary Calcium for Ruling Out Atherosclerotic Etiology of Disease in Symptomatic Patients**

In certain clinical situations such as patients presenting with chest pain or other symptoms, it is uncertain whether the symptoms are potentially due to CHD. Coronary calcium measurement has been proposed as a method that can rule out CHD in certain patients if the coronary calcium value is zero. Since coronary disease can only very rarely occur in the absence of coronary calcium, the presence of any coronary calcium can be a sensitive but not specific test for coronary disease. False positives occur because the calcium may not be causing ischemia or symptoms. The absence of any coronary calcium can be a specific test for the absence of coronary disease and direct the diagnostic workup toward other causes of the patient’s symptoms. In this context, coronary calcium measurement is not used to make a positive diagnosis of any kind but as a diagnostic “filter” used to rule out an atherosclerotic cause for the patient’s symptoms.

For example, in a study by Laudon et al. in the emergency department setting, 51% (133/263) patients with chest pain and low-to-moderate probability of CAD had calcium scores of zero. One of these patients was found to actually have coronary disease. The others were presumed to not have coronary disease, and it is claimed that these patients could have been safely discharged from the emergency department. However, the study is not rigorous in its methods regarding the alternative workup of potential CAD in the emergency department or in the long-term follow-up of patients.

Evidence regarding the use of coronary calcium scores in the assessment of symptomatic patients has been reviewed in a 2007 clinical consensus co-written by the American College of Cardiology Foundation (ACCF) and the American Hospital Association (AHA). Calcium scores have similar sensitivity and specificity to other tests such as exercise single-photon emission computed tomography (SPECT) and stress echocardiography for the diagnosis of anatomic obstructive CHD. It is difficult to determine the validity of these diagnostic performance characteristics given the possible referral and confirmation biases. If the performance of the reference standard for coronary disease such as angiography is based upon the results of the diagnostic tests under study, diagnostic test characteristics are biased.

**Impact on Cardiac Risk Factor Profiles**

There have been a small number of randomized, controlled trials (RCTs) of the impact of EBCT on cardiac risk factors. In 2012, Seamus et al. published a meta-analysis of RCTs that evaluated the impact of coronary calcium scores on cardiac risk profiles and cardiac procedures. There were 4 trials identified with a total of 2,490 participants; the individual trials ranged in size from 50-1,934 patients. The authors pooled data from 4 trials on the impact of calcium scores on blood pressure (BP), 3 on the impact on low-density
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Lipoprotein (LDL), and 2 on the impact on high-density lipoprotein (HDL). Pooled analysis did not show a significant change in any of these parameters as a result of calcium scores. Similarly, in 4 studies that looked at the rates of smoking cessation following calcium scores, there was not significant change found. There were 2 studies that included rates of coronary angiography and 2 studies that included rates of revascularization. Pooled analysis of these studies did not show a significant change following measurement of coronary calcium.

Two RCTs representative of this evidence are discussed further here. O'Malley et al. randomized 450 subjects to receive EBCT or not and assessed outcomes 1 year later for change in Framingham Risk Score. Thus, EBCT was to be used as a guide to refine risk in patients and possibly provide motivation for behavioral change. The study was not powered for clinical endpoints. Electron-beam computed tomography did not produce any benefits in terms of a difference in Framingham risk score at 1 year.

An RCT was published in 2011 evaluating the impact of CT scanning for coronary artery calcium on cardiac risk factors. A total of 2,137 healthy individuals were randomized to CT scanning or no CT scanning and followed for four years. At baseline, both groups received one session of risk factor counseling by a nurse practitioner. The primary outcome was change in 12 different cardiac risk profile measures, including BP, lipid and glucose levels, weight, exercise, and the Framingham risk score. At the 4-year follow-up, there was differential dropout among the groups, with 88.2% of follow-up in the scan group versus 81.9% in the no-scan group. Results demonstrated differences in 4 of the 12 risk factor measurements between groups: systolic BP, LDL, waist circumference, and mean Framingham risk score.

This trial highlights the potential benefit of coronary artery calcium screening in modifying cardiac risk profile but is not definitive in demonstrating improved outcomes. Limitations of this study include different intensity of interventions between groups and differential dropout. It is possible that the small differences reported in the trial were the result of bias from these methodologic limitations. In addition, this trial does not compare the impact of other types of risk factor intervention, most notably more intensive risk factor counseling. Finally, the generalizability of the findings is uncertain given that this was a volunteer population that may have been highly motivated for change.

Future Research Needs
The current research mainly establishes that coronary artery calcium screening improves risk prediction for CAD. The 2011 RCT suggests that scanning may favorably impact cardiac risk profiles but is not sufficient in itself to demonstrate improved outcomes. In order to demonstrate that use of calcium scores improves the efficiency or accuracy of the diagnostic workup of symptomatic patients, rigorous studies that define exactly how coronary calcium scores are used in combination with other tests in the triage of patients would be necessary. Study designs need to explicitly evaluate diagnostic strategies that compare one strategy which uses calcium scores to an alternative which does not use calcium scores. Ideally, patient outcomes and resource utilization would need to be prospectively evaluated.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received through two physician specialty societies and four academic medical centers on this policy (the version approved in July 2008) in November 2008. While the various
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Physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. The majority of those providing input agreed with the conclusions of this policy (investigational) as approved in July 2008.

Clinical input received in 2011 was mixed regarding the investigational status of coronary artery calcium screening. Input was received from 7 sources, 5 academic medical centers, and 2 specialty societies. Four of the 7 reviewers agreed with the investigational status, while 3 dissent. The dissenters primarily cited evidence on the accuracy of scanning for risk prediction of CAD. The American College of Cardiology also cited the 2011 RCT as evidence of the impact of scanning on risk factor profile.

Summary
There is extensive evidence on the predictive value of coronary artery calcium screening for cardiovascular disease, and this evidence demonstrates that scanning has incremental predictive accuracy above traditional risk factor measurement. High-quality evidence is lacking comparing the use of coronary artery calcium screening to other methods of enhanced risk prediction, and as a result, there is uncertainty as to which methods are preferred in specific populations. Limited evidence from clinical trials suggests that scanning may lead to improved risk factor profiles, but this finding has not been consistent and methodologic limitations preclude definitive conclusions on this question.

Evidence-based guideline statements regarding calcium score measurement give, at best, a reserved recommendation in favor of the use of EBCT and recognize the incomplete evidence base that supports those recommendations. Review of several guidelines shows disagreement regarding the utility of calcium score measurement. The U.S. Preventive Services Task Force (USPSTF) review highlights the inconsistency of the relative risk of coronary disease associated with calcium scores, thus making risk estimates based on it imprecise. Because of the lack of high-quality evidence demonstrating improved outcomes and the lack of strong recommendations from authoritative sources, the use of CT to detect coronary artery calcification is considered investigational.

References
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Diagnosis and screening for coronary artery disease with electron beam computed tomography. TEC Assessments 1998; Volume 13, Tab 27.
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Policy History

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10/19/2002 Medical Policy Committee review
10/21/2002 Managed Care Advisory Council approval
10/05/2004 Medical Director review
11/16/2004 Medical Policy Committee review. Format revision. No substance change to policy
11/29/2004 Managed Care Advisory Council approval
07/07/2006 Format revision, including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/01/2006 Medical Director review
11/05/2008 Medical Director review
11/18/2008 Medical Policy Committee approval. No change to coverage eligibility.
01/01/2010 Coding revision.
11/04/2010 Medical Policy Committee approval
11/16/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility.
02/01/2011 Coding revision
11/03/2011 Medical Policy Committee approval
11/16/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.
11/01/2012 Medical Policy Committee approval
11/28/2012 Medical Policy Implementation Committee approval. No change to coverage eligibility.
11/07/2013 Medical Policy Committee review
11/20/2013 Medical Policy Implementation Committee approval. Title changed from “Electron Beam/Spiral Computed Tomography to Detect Coronary Calcification” to “Computed Tomography to Detect Coronary Calcification”. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2014

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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